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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,015	08/23/1999	Carsten Korth	DT-3073	2058

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	19

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/380,015	KORTH ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-76* is/are pending in the application.

4a) Of the above claim(s) *50,55-66,69-71 and 73-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-49 and 72* is/are rejected.

7)☒ Claim(s) *51-54,67 and 68* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election of Group I in Paper No. 18 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Applicant is required to update the status (pending, allowed, ect.) of all parent priority applications in the first line of the specification.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Correction is required.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Claim Objections

Claims 51-54, 67 and 68 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim or

refer to two sets of claims having different features. See MPEP § 608.01(n). Accordingly, the claims 51-54, 67 and 68 have not been further treated on the merits.

Claim 40 is objected to because of the following informalities: The claim indicates that the normal prion protein (PrP^{Sc}), this does not match the abbreviation of normal host prion protein (PrP^{C}) provided in the specification page 2. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 40-49 and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Pruisiner et al. (U.S. Pat. No. 5,846,533) as evidence by Billeter et al. (PNAS 1997).

The instant invention is drawn to a monoclonal antibody or fragment thereof that is abele to bind PrP^{Sc} (native disease specific prion protein) while not binding PrP^{C} (normal cellular prion protein) (claim 40). This antibody, which meets the previous limitation, will also bind at least one of sequences of SEQ ID NO 7-9 (claims 41). The instant inventions also contemplates monoclonal antibodies to prion proteins that bind SEQ ID Nos: 5 and 6 (claim 42). The monoclonal antibody will bind soluble, insoluble, oxidized or reduced prion protein (claims 43,

44, 49). The antibody can be label so that it may be used for detection. Additionally, the monoclonal antibody will be used to formulate a pharmaceutical preparation (claim 72).

The instantly claimed monoclonal antibodies are produced by injecting a prion knock out mouse with a recombinant prion protein molecule. The spleen cells are collected and hybridomas are created by fusing the B-cells with a myeloma cell. These antibodies are then screened for their reactivity against a peptide library.

The mere recitation of newly-discovered function or property, inherently possessed by things in the prior art, does not cause the claim drawn to those things to distinguish over the prior art (See *In re Best, Bolton, and Shaw* 195 USPQ 430 (CCPA 1977), *In re Schreiber* 44 USPQ2d 1429)

> MPEP 2131.01 Normally, only one reference should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:
> (A) Prove the primary reference contains an "enabled disclosure; "
> (B) Explain the meaning of a term used in the primary reference; or
> (C) Show that a characteristic not disclosed in the reference is inherent
> Extra references or evidence can be used to show an inherent characteristic of the thing taught by the primary reference. "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation.

Pruisiner et al. (U.S. Pat. No. 5,846,533) discloses monoclonal antibodies D4, R2, 6D2, D14, R1 and R10 (see column 38, lines 20-21). The antibodies were made by injecting a prion knock out mice with purified prion rods (see column 28, line 15, to column 29, line 8; example 1

and claim 8). The antibody secreting B-cells are then isolated from spleen and these cells are used to create the phage display library (examples 4 and 5). The antibodies are obtained by panning the phage display library against PrP^C, only those phage that do not bind PrP^C were evaluated for their ability bind to PrP^{Sc} (see example 11, claim 1 and figures 9 and 10). As the antibodies were screened the prion protein was either insoluble (ie. bound to the surface) or soluble when evaluating the ability of the monoclonal antibody to immunoprecipitation the prion protein. The reference also contemplates using the antibodies as a treatment (see column 10, lines6-27; column 21 lines 25-41). The antibodies can be used in immunoaffintiy assays or coupled onto other surfaces (coupled to other molecules). The specific epitope bindings was not determined for the monoclonal antibodies disclosed, nor were the antibodies tested for their binding to recombinant, reduced or oxidized prion protein. The reference discloses antibodies (claim 3) that are able to bind cow, horse, dog, human, chicken and cat prions.

Antibody binding is dependent on the epitope structure, which is inherent to the amino acid sequence. Antibodies my bind linear epitopes or three-dimensional epitopes. The structure of a molecule is determined by the amino acid sequence, Billetter et al. (PNAS 1997, figure 2) shows the predicted NMR structure of a prion protein. Only epitopes that are located on the outside of a molecule would be accessible for antibody attachment. The epitopes disclosed in SEQ ID NO 5-9 are found on the outside of the prion molecule and therefore would accessible for antibody attachment. The epitopes are an inherent structural feature of the prion protein.

Therefore, the instant invention is anticipated by Pruisner et al. as evidenced by Billeter et al.

Allowable Subject Matter

The specific deposited antibody producing clones would be allowable DSM ACC2295 (34C9), DSM ACC2296 (6H4) and DSM ACC2298 (15B3) would be allowable

Conclusion

Claims objected to and not further examined on the merits 51-54, 67 and 68.

Claims rejected 40-49,

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D. 11/18/02